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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,727	09/26/2005	Jochen Wonschik	3968.150	8867

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,727	WONSCHIK ET AL.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on June 24, 2008 is acknowledged. Claims 1-11 and 13-21 remain pending in this application. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 11, 14-17, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearce (US 20050100640) in view of Halik et al. (US Patent 4,241,092) and further in view of Stapler et al. (US Patent 5,286,496).

Pearce discloses edible microcapsules comprising one ore more layers of film that is orally soluble and disintegrates quickly upon placement in a human mouth without leaving substantial residue that can be felt by the human tongue or which needs to be swallowed or ejected from the mouth (paragraph 0004). Orally soluble edible films can include water and a film forming agent. Additives including plasticizing agents and flavoring agents may be added (paragraph 0009). Film forming agents include sodium alginate, gelatin, and natural gums in the amount ranging from 0.01% to about 99% of the film (paragraph 0010). Although the gellan gum is not particularly disclosed by Pearce, gellan gum is frequently uses as a food additive as a thickener, emulsifier or

stabilizer. Therefore, it would have been obvious to person of ordinary skill in the art to have included it as a functional equivalent to the gums specifically disclosed, furthermore, answers.com discloses one only need approximately half the amount of gellan gum as agar to reach an equivalent gel strength.

Plasticizers for use include sorbitol, propylene glycol, and glycerol (paragraph 0027). The plasticizer may be present in the range of 0% to about 20% dry weight of the film composition (paragraph 0026).

Pearce discloses the films may be used to encapsulate non-film edible materials including flavored oils, medicaments, breath fresheners, antiseptic, antimicrobial, nutracueticals, candy, and the like (paragraph 0102). The amount of flavoring is dependent on preference but is generally in the range of 0.1 to about 30% (paragraph 0046). The microcapsules can be made by various surface tension methods. They generally consist of an outer shell and an inner phase or core (paragraph 0327). The diameter of the microcapsule is from about 2-6 mm but can be larger (paragraph 0328). The microcapsules can be dried to remove the carrier fluid or moisture from the shells or cores (paragraph 0329).

Regarding claim 14, artificial sweeteners including, aspartame, acesulfame potassium, saccharine and sucralose can be used (paragraphs 0047-0057).

Pearce does not disclose the thickness of the shell, a seamless solid coating, or ratio of shell thickness to shell diameter.

Halik discloses a coating of edible sugar, either in hard or powder form can be applied to the outer coating of a candy (column 2, lines 37-45). Sorbitol is disclosed as the preferred coating material (column 2, lines 59-60).

It would have been obvious to one of ordinary skill in the art to have included the sugar coating of Halik onto the capsules of Pearce, since Halik discloses sorbitol will remain in the metastable state, i.e. it is easily supercooled, becoming hard with only minor amounts of crystallization if not stirred. When sorbitol is melted and held in that condition until substantially all the water is driven off and then supercooled, it forms a viscous glassy melt which can be easily kneaded at about 100F (column 2, line 61 through column 3, line14). Sorbitol is present in the amount of up to 60% (column 3, line 25-27). The coating can be applied by pan coating (column 5, lines 61-65). Pan coating would result in a seamless coating application.

Stapler discloses, "microcapsules which contain breath control actives/antimicrobials in the core of the microcapsule along with an organic diluent as well as in the shell of the microcapsule" (column 1 line 65 to column 2, line 2).

Additionally, "the shell material of the microcapsules can be any materials which are suitable for ingestion as well as retention in the oral cavity, including gelatin, polyvinyl alcohols, waxes, gums, sucrose esters and sugar candy type materials used in cough drops and mints" (column 2, lines 11-16). The thickness of the shell is discloses in the range of 30um to 2mm (column 2, lines 19-20). The particle diameter is in the range of about 2mm to about 9mm (column 2, lines 23-25). Therefore the ratio of

thickness of the shell to particle diameter would fall within the claimed values of 0.004 to 0.04:1.

Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of microcapsules for use in the oral cavity having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. See In re Russell, 439 F.2d 1228 169 USPQ 426(CCPA 1971).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated the dimensions of Stapler into the product of Pearce in order to provide improved microcapsules which do not release the contents of the capsule prematurely and allow for the active agents in the core to be provide efficacy and/or enhanced sensory perception (Stapler, column 1, lines 15-50).

Claims 6-9, 13, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearce (US 20050100640) in view of Halik et al. (US Patent

4,241,092) and Stapler et al. (US Patent 5,286,496) in view of Alamian et al. (US Patent 6,770,311).

The combined teachings of Pearce, Halik, and Stapler is discussed above and applied in the same manner.

Pearce and Stapler do not disclose the source of gelatin.

Alamian discloses, "granules having a shell with a gelled center, derived from an aqueous mixture containing food grade encapsulation materials, such as water-soluble carregeenans or gelatin. The mixture is introduced in the form of droplets into food grade oil, the temperature of which, at least in its lower layers, is below the temperature at which the droplets congeal to form granules. The thus-formed granules have an outside shell" (column 1, line 57 through column 2, line 5).

Additionally, Alamian discloses, "the food grade encapsulation materials must be able to form a shell, such as gelatin, beef gelatin, fish gelatin, pork gelatin, alginates, and gellan gum" (column 2, lines 34-52).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Stapler and Rowe with the teachings of Alamian since the encapsulation material must have the ability to form a shell or membrane, be stable at temperatures between –10C to 80C and must be light. It would be within the knowledge of one of ordinary skill in the art to select a gelatin, which would create a shell with the qualities desired. Additionally, it is the examiners position that each type of gelatin would have different bloom values and different gel

points; therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have selected the gelatin to best fit the qualities to be obtained.

A person of ordinary skill in the art would have a reasonable expectation of success in making the claimed capsules since all cited references teach capsules with a gelatin shell.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pearce (US 20050100640) in view of Halik et al. (US Patent 4,241,092) and Stapler et al. (US Patent 5,286,496) in view of Greenberg (US Patent 5,378,131).

The combined teachings of Pearce, Halik, and Stapler is discussed above and applied in the same manner.

Pearce, Halik, and Stapler do not disclose the use of the specific sweeteners of claim 10.

Greenberg discloses a chewing gum comprising sweeteners, including sucralose, aspartame, salts of acesulfame, thaumatin, and saccharine and its salts (column 6, lines 1-5).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Stapler and Rowe with the sweeteners taught by Greenberg, since Greenberg discloses, "in order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate the artificial sweetener" (column 6, lines 6-9).

One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success since Stapler and Rowe both disclose the use of a sweetener and Greenberg discloses the use high intensity artificial sweeteners to be encapsulated.

Response to Arguments

Applicant's arguments with respect to the rejection(s) over Pearce and Stapler have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Pearce, Halik, and Stapler. Applicant's arguments regarding the individual references are discussed below.

Regarding Applicants arguments relating to the Pearce reference, Applicant argues Pearce is drawn to films and tapes and does not mention seamless microcapsules until paragraph 0326. It is further argued it is not disclosed or suggested the microcapsule shell is coated and the methods of making the films and their conversion into soft gels or two piece tablets is treated separately from the formation of the microcapsules. While it is conceded that the methods of making the two different products (i.e. the tapes versus the microcapsules), the components from which the final products are made are the same. Thereby meeting the limitations of the instant claims. The microcapsules are disclosed as being made from the same components are the films, but by a different method.

Applicant did not provide any specific arguments regarding the Stapler reference other than to state that it does not cure the deficiencies of Pearce.

Regarding the Alamiam and Schlameu reference, Applicant is arguing limitations that are not present in the claims (i.e. stickiness). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues the Greenberg reference is not relevant because it does not affect novelty of pending claim 1. The examiner disagrees. The claims are rejected over a combination of references. Greenberg is relied on for the teachings of specific flavorings not disclosed in the other references. Therefore, the teachings of Greenberg are considered relevant.

Conclusion

Due to the new grounds of rejection presented in this office action, this action is made Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615